

REMARKS

Claims 1-6, 10-11, 13-16 and 18 remain pending in this application, of which claims 1, 10 and 14 have been amended herein. No new matter has been added. Based on the foregoing amendments and following remarks, reconsideration and allowance of the application is respectfully requested.

Information Disclosure Statement

A supplemental information disclosure statement is submitted herewith, including an additional office action and response in related US Patent Application S.N. 10/669,203. Applicant respectfully requests consideration of the documents cited in the information disclosure statement.

Claim Rejections - 35 U.S.C. §103

Claims 1-2 and 6, stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 6,397,107 ("Lee") in view of U.S. Patent No. 5,749,894 ("Engelson"). Applicant respectfully traverses these rejections, since the combination of Lee and Engelson does not disclose or suggest each of the acts required by these claims, as amended herein.

The Supreme Court has addressed the issue of obviousness in KSR International vs. Teleflex Inc., 550 U.S. (2007), in which the Court reiterated the requirement that a rejection on "obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" (KSR at page 14 of the slip opinion), and further that a "fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex parte reasoning. (KSR at page 17

of the slip opinion). Also, while not specifically addressed in KSR, the prior art references, when combined, must still teach or suggest all the claim limitations (See MPEP §2143).

Independent claim 1 has been amended to recite a method for embolizing a target site in a vasculature of a body, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body, the vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating; and delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

Lee discloses deploying a vaso-occlusive device in a vascular malformation and delivering high frequency energy from outside the body to heat the occlusive device that, in turn, heats the tissue of the malformation to coagulate and contract around the device. (Col. 2, lines 50-65). There is no disclosure or suggestion in Lee that the vaso-occlusive device comprises a therapeutic bioactive agent coating or a polymeric material coating substantially covering a bioactive agent coating, or that heating the vaso-occlusive device at least partially melts or softens a polymeric material so that a bioactive agent is released or activated at the treatment site. Nor does, Engelson disclose or suggest these missing claim limitations.

Engelson discloses deploying a vaso-occlusive device that is heated preferably by a light-emitting device inside the blood vessel in order to reform or melt a polymer coating over the device that adheres to and stabilizes the vaso-occlusive device (Col. 1, lines 15-

20, Col. 3, line 64 to Col. 4, line 55, Col. 5, lines 5-17, Col. 9, lines 31-41). Again, there is no disclosure or suggestion in Engelson that a therapeutic bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

Thus, even if a person skill in the art were to combine the teachings of Lee and Engelson, the resulting method would include deploying a vaso-occlusive device having a single coating of polymeric material at a target site (Engelson) and delivering energy from a high frequency energy located outside the body (Lee) to thereby heat the vaso-occlusive device at the target site to reform or melt the polymeric coating and stabilize the vaso-occlusive device (Engelson). However, such combination will not produce a method for embolizing a target site in a vasculature of a body, including detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a vasculature of a body, the vaso-occlusive device comprising a therapeutic bioactive agent coating and a polymeric material coating substantially covering the bioactive agent coating; and delivering energy from an energy emitting element located outside the body to thereby heat the vaso-occlusive device at the target site, wherein the polymeric material at least partially melts or softens so that the bioactive agent is released or activated at the treatment site when the vaso-occlusive device is heated.

For at least these reasons, Applicant respectfully submits that independent claim 1 is patentable over the combination of Lee and Engelson. Dependent claims 2 and 6 incorporate all of the limitations of independent claim 1, and thus are believed to be patentable over Lee and Engelson for at least the same reasons as claim 1.

Claims 3-4, 10 and 13 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Lee and Engelson, in further view of U.S. Pub.

2004/0215124 (“Yamasaki”). The office action states that the combination of Lee and Engelson disclose the claimed invention except having a magnetic resonance imaging (MRI) device to apply magnetic field (Yamasaki). Applicant respectfully disagrees, in view of the amendments to the claims.

As discussed above, the combination of Lee and Engelson does not disclose or suggest all of the limitations of independent claim 1, and neither disclose or suggest the all the limitations of independent claim 10 for the same reasons. In particular, the combination of Lee and Engelson does not disclose the acts of “heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent.” Nor does Yamasaki teach or suggest these missing claim limitations.

Yamasaki discloses introducing an irritant in serum form into the aneurysm, causing the aneurysm to shrink *“over the course of several days or weeks”* (Yamasaki, paragraph 62 - 66). Although, MRI may be used to cure the irritant in Yamasaki, a method combining Lee, Engelson with Yamasaki, would not yield all the claims limitations of claims 3-4, 10 and 13. Certainly, Engelson does not suggest why such modification of a MRI use would be desirable because Engelson’s method requires a light-emitting device in order to reform the polymers, and does not release or activate therapeutic bioactive agents. Furthermore, even if a person skilled in the art would consider constructing a device or performing a process based on the combination of Lee, Engelson, and Yamasaki, such combination would still not teach or suggest a method for embolizing a target site in a body, comprising detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-

occlusive device at a target site in a body; positioning the body in a magnetic resonance imaging ("MRI") device; and activating the MRI device to apply a variable magnetic field to the body, thereby heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent.

For at least these reasons, claims 3-4, 10 and 13 are believed patentable over the combination of Lee, Engelson and Yamasaki.

Claim 5 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lee in view of Engelson, and further in view of U.S. Patent No. 6,740,094 ("Maitland"). Applicant respectfully disagrees.

Maitland discloses the activation and expansion of a shape memory actuator when heated to remove blockages in a blood vessel, wherein the energy delivered to the actuator may be ultrasounds waves (Col 6, lines 26-57). Neither Lee nor Engelson disclose all the limitations of independent claim 1 as discussed above, and having an energy source comprising an ultrasound device, as disclosed in Maitland, does not provide the missing claim limitation. Thus, claim 5 is believed patentable over the combination of Lee, Engelson and Maitland.

Claim 11 stands rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over the combination of Lee and Engelson, in further view of Yamasaki and still in further view of U.S. Patent No. 5,405,322 ("Lennox"). Lennox discloses a method for treating an aneurysm by heating the aneurysm wall with an electrical current generated between two electrodes located in a device inserted into the blood vessel (Col 4 lines 13-30). Again, the combination of Lee, Engelson and Yamasaki does not disclose or suggest a method for

embolizing a target site in a body, comprising detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device at a target site in a body; positioning the body in a magnetic resonance imaging ("MRI") device; and activating the MRI device to apply a variable magnetic field to the body, thereby heating a highly resistive element in the vaso-occlusive device and at least partially melting or softening a polymeric material exterior coating on the vaso-occlusive device to thereby release or activate an underlying therapeutic bioactive agent, and including the thermal source of Lennox does not provide the missing claim limitations. Thus, claim 11 is believed patentable over the combination of Lee, Engelson, Yamasaki and Lenox.

Claims 14 and 15 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lee in view of Yamasaki. Applicant respectfully traverses this rejection, since the combination of Lee and Yamasaki does not disclose or suggest the acts required by these claims, as amended herein. The office action indicates that it would have been obvious to provide a highly resistive element comprising a ferrous material to the device of Lee to heat the highly conductive material used in vaso-occlusive device. However, neither Lee nor Yamasaki discloses or teaches, a method for embolizing an aneurysm in a body, comprising detaching a vaso-occlusive device from a delivery catheter to thereby deploy the vaso-occlusive device in an aneurysm, the device including a highly conductive coil forming a lumen, a highly resistive element at least partially disposed in the lumen; a therapeutic bioactive agent coating of the coil and a polymeric material coating substantially covering the bioactive agent coating; and applying magnetic field energy to the device from an energy emitting element located outside of the body, thereby heating the highly resistive element and, by way of convective heat transfer from the highly resistive element, heating

the coil thereby at least partially melting or softening the polymeric material and releasing or activating the bioactive agent, as recited in claim 14.

For at least these reasons, independent claim 14 is believed patentable over the combination of Lee in view of Yamasaki. Dependent claim 15 is also believed patentable over such combination, for at least the same reasons.

CONCLUSION

In view of the foregoing amendments and remarks, allowance of all remaining claims is respectfully requested. If the Examiner believes that a telephone interview could expedite resolution of any remaining issues, she is encouraged to contact Applicant's undersigned representative at the phone number listed below.

Respectfully submitted,
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